REMARKS

By the present amendment, claims 23 and 26-27 have been canceled, and new claim 30 corresponding to claim 27 but dependent on claim 29 has been added.

Claims 28-30 are pending in the present application.

As a preliminary, Applicant and Applicant's representative thank the Examiner for the personal interview which was held on November 22, 2004.

In the Office Action, claims 23, 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, as not enabled, and under 35 U.S.C. 112, second paragraph as indefinite.

Since claims 23 and 26-27 have been canceled, it is submitted that the rejections are moot.

Next, in the Office Action, claims 23 and 26-29 are rejected as obvious over U.S. Patent No. 6,369,046 to Schatzberg et al. ("Schatzberg") under 35 U.S.C. 103(a).

Reconsideration and withdrawal of the rejection with respect to claims 28-29 is respectfully requested. As discussed during the personal interview, Schatzberg fails to teach or suggest detecting Alzheimer's disease based on analysis of cortisol levels in cerebral spinal fluid (CSF).

Specifically, Schatzberg mentions cerebro-spinal fluid only three times.

The first time, Schatzberg mentions the possibility of "decreased levels of APPs in cerebrospinal fluid" in the diagnosis of Alzheimer's disease (Schatzberg at col. 8, lines 50-51). The second time, Schatzberg lists "cerebrospinal fluid assays showing low levels of Abeta42 and high levels of tau" as potentials markers for Alzheimer's disease (Schatzberg at col. 8, lines 55-56). In both cases, Schatzberg does not suggest using cortisol levels in CSF in the diagnosis and assessment of Alzheimer's disease. Rather, Schatzberg focuses on determining "[v]arying

levels of blood cortisol" (see Schatzberg at col. 13, lines 10-11). In the only Example of Schatzberg, only blood cortisol is measured (see Schatzberg at col. 22, lines 43-62).

The third time CSF is mentioned in Schatzberg, the reference indicates that, in the treatment of dementia by administration of a glucocorticoid receptor antagonist, "[l]ower dosages can be used, particularly when the drug is administered to an anatomically secluded site, such as the cerebral spinal fluid (CSF) space" (Schatzberg at col. 21, lines 4-7). Thus, Schatzberg mentions CSF, in passing, as a possible site for drug (i.e., mifepristone) administration, but Schatzberg always measures cortisol levels in blood for the diagnosis of Alzheimer's disease-related dementia.

In summary, in its diagnosis and treatment methods, Schatzberg measures cortisol levels in blood only.

In contrast, in the presently claimed invention, a level of cortisol in the cerebro-spinal fluid (CSF) of the patient is measured or detected, as recited in respective present claims 28-29, so that Alzheimer's disease can be identified or treated, as further recited in respective present claims 28-29. An advantage of this feature is that early detection of Alzheimer's disease through measurement of cortisol levels can be facilitated. This feature of the presently claimed invention and its advantages are not taught or suggested in Schatzberg, and therefore, the present claims are not anticipated by, and not obvious over, the cited reference.

In view of the above, it is submitted that the art rejection should be withdrawn.

In the event there is, in the Examiner's opinion, any outstanding issue and such issue may be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number listed below.

In the event this paper is not considered to be timely filed, the Applicants hereby petition for an appropriate extension of the response period. Please charge the fee for such extension and any other fees which may be required to our Deposit Account No. 50-2866.

Respectfully submitted,

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